UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 14 2008

Ms. April Zasmbelli-Weiner
Sterilex Corporation
11409 Cronhill Drive
Suite L
Owings Mills, MD 21117

RECEIVED JUL 23 2008

Subject: Sterilex Ultra Powder
EPA Registration No.: 63761-5
Amendment Date: November 6, 2007
EPA Receipt Date November 11, 2007

Dear Ms. Weiner,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- One-Step Disinfection Claim

Conditions
Revise the label as follows:

1) Since a protocol and data were not sent to support a biofilm claim on hard nonporous surfaces, you must revise the 3rd bullet on page 1 to read "Kills biofilm bacteria in dental unit water lines."

2) Revise the nomenclature for *Salmonella choleraesuis* (ATCC 10708) to reflect the new designation of "*Salmonella enterica*."

3) Revise the "Barber and Salon Instruments and Tools" directions on page 6 by qualifying rollers as hard nonporous by stating "*plastic*" rollers. Also, revise step 5 by deleting "should" and stating "*must*" so that the directions are incompliance with PR Notice 2000-5, Mandatory Labeling.

4) Revise the "Precleaning Whirlpool Bathtubs" directions to by stating:

After using the whirlpool unit, drain and refill with fresh water to just cover the intake valve. Add 50 g Ultra Powder per Liter of hot tap water. Briefly start the pump to circulate the solution. Turn off the pump. Wash down the sides, seat of the chair, and any/all related equipment with a sponge or

brush. Drain solution from the unit and rinse cleaned surfaces and equipment with fresh water.

Acceptable Data

Data Requirement	Means of Support	Status
AOAC Use Dilution Method–S. aureus, P. aeruginosa, S. enterica	MRID No. 472803-01	Acceptable, 50 gm in 1L of water for 10 min in 5% soil and 400 ppm hard water

General Comments

The Confidential Statement of Formula dated November 2, 2007 is acceptable. It is incompliance with PR Notice 91-2 and in agreement with the label.

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosures: Stamped Label
Efficacy Data Evaluation